REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and the following remarks.

I. Status of the Claims

Claims 1, 3-6 and 9-22 are currently pending in the application, with claim 1 being the independent claim. Claims 2 and 7-8 were previously canceled. Claims 11 and 22 are amended.

Claim 11 is amended to delete the phrase "as emulsifiers".

Claim 22 is amended to replace the phrase "fat phase" with the phrase "medium-chain triglycerides" and revised to correct lack of antecedent basis. Support for the amendments to claim 22 may be found throughout the specification, including paragraph [0042] at page 13.

These amendments do not introduce any new matter into the application and their entry is respectfully requested.

II. The Rejection Under 35 U.S.C. § 112, First Paragraph

The Office Action, at pages 2-5, rejects claims 21-22 as allegedly failing to comply with the written description requirement. Specifically, the Office alleges that the specification and claims as originally filed fails to provide adequate written description for (a) the use of eicosapentaen acid and/or docosahexaen acid obtained from refined fish oil concentrate; and (b) for the melting of the fat phase. Applicant respectfully traverses this ground of rejection.

Applicant asserts that the specification as originally filed provides full support for the language in the claims. With regard to the use of eicosapentaen acid and/or docosahexaen acid obtained from refined fish oil concentrate, Applicant wishes to bring the Examiner's attention to paragraph [0028] at page 8 of the specification, which defines eicosapentaen acid and docosahexaen acid as "***long-chain polyalkylene fatty acids***", and Table 1 at page 12 of the specification, which lists ***fish oil concentrate*** among the fats of the composition of the invention,

including legend [a] on the same page which states the following: "[a] ***Highly-purified fish oil concentrate*** *stabilized with RRR-α-tocopheryl and ascorbyl palmitate* ***which contains at least 30% long-chain omega-3-polyalkylene fatty acids***" (emphasis added). Further, paragraph [0036] at page 10 of the specification refers to "*a highly purified fish oil concentrate*" and paragraph [0042] at page 13 discloses that "*a fish oil concentrate* and the other fat-soluble ingredients are added to the liquid mixture no sooner than immediately before homogenisation" (also quoted on page 4 of the Office Action).

Thus, the specification provides full support for eicosapentaen acid and/or docosahexaen acid obtained from refined fish oil concentrate. Accordingly, Applicant has sufficiently disclosed the invention to meet the written description requirement. The rejection is therefore improper and should be withdrawn.

With regard to the melting of the fat phase, as acknowledged by the Office, paragraph [0042] at page 13 of the specification teaches the melting of the medium-chain triglyceride (MCT) fat, and thus provides support for the melting of the fat phase. Nevertheless, solely to advance prosecution, and not in acquiescence with the rejection, the foregoing amends claim 22 to replace the phrase "fat phase" with the phrase "medium-chain triglycerides". Accordingly, the rejection is moot.

Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

III. The Rejections Under 35 U.S.C. § 112, Second Paragraph

The Office Action, at pages 5-7, rejects claims 11-13 and 22 as allegedly being indefinite. Specifically, the Office alleges that the phrase "wherein the fat phase of the composition further comprises as emulsifiers, mono- and diglycerides of edible fatty acids, fat-soluble vitamins, β-carotene, and butter flavourings " in claim 11 is unclear. Further, the Office alleges that the

phrase "the aqueous phase" in claim 22 lacks antecedent basis. Applicant respectfully traverses this ground of rejection.

Solely in the interest of advancing prosecution, the foregoing amends claim 11 to delete the phrase "as emulsifiers" and claim 22 to replace the phrase "the aqueous phase" with the phrase "an aqueous phase". Accordingly, the rejections are moot. Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

IV. The Rejections Under 35 U.S.C. § 103(a)

A. The Rejection Over Alexander in Light of Brenna

The Office Action, at pages 7-11, rejects claims 1, 3, 6, 9, 14-19 and 21 under 35 U.S.C. § 103 as allegedly being unpatentable over Alexander *et al.* (EP 0691079 A2; 1996) ("Alexander") in light of Brenna JT ("Efficiency of Conversion of [alpha]-Linolenic Acid to Long Chain n-3 Fatty Acids in Man", *Current Opinion in Clinical Nutrition and Metabolic Care, 5(2)*:127-132, March 2002; abstract only) ("Brenna"). Specifically, the Office alleges that the docosahexaenoic acid and eicosapentaenoic acid are inherently present in the compositions disclosed by the prior art, since the art allegedly recognizes that these acids are conversion products of α-linolenic acid, and the amount ranges of different ingredients may be determined by the artisan skilled in the art by routine experimentation. Applicant respectfully traverses this ground of rejection.

1. The Cited References Fail to Teach Each and Every Element of the Claimed Invention

Alexander discloses a composition comprising canola oil, olive oil, high-oleic safflower oil and soy oil, and teaches that long-chain triglycerides are supplied by these oils (*see* paragraph [0046] at page 4). Further, Alexander teaches that the composition may comprise 4 to 10% of α-linolenic acid. Alexander fails to disclose or suggest at least two essential elements of the claimed invention.

First, Alexander fails to teach or suggest a composition comprising *0.5 to 2% eicosapentaen acid and/or docosahexaen acid*, as presently claimed.

Second, with regard to claim 21, the composition disclosed by Alexander contains canola oil, olive oil, high-oleic safflower oil and soy oil, which are vegetable oils, **not** fish oils. Accordingly, Alexander fails to teach a composition comprising *0.5 to 2% eicosapentaen acid and/or docosahexaen acid from refined fish oil concentrate*, as claimed in the present application.

Thus, the cited reference fails to disclose the claimed invention.

Brenna fails to remedy the deficiencies of Alexander described above, as the reference fails to disclose a composition comprising 0.5 to 2% eicosapentaen acid and/or docosahexaen acid, let alone a composition comprising 0.5 to 2% eicosapentaen acid and/or docosahexaen acid obtained from refined fish oil concentrate.

Thus, at least for the reasons stated above, the cited references fail to disclose or suggest the claimed invention.

2. There is no Reason to Combine the Known Elements in the Fashion Claimed

The Office contends that although DHA and EPA are not explicitly taught by Alexander, "the art recognized such acids as conversion products of alpha-linolenic acid and, therefore, such acids are necessarily present by the teaching of plant oils that contain linolenic acid in an amount of 4-10% which, according to the amount of conversion disclosed by Brenna, meets Applicant's requirement of 0.5% docosahexaenoic and/or eicosapentaenoic acid" (Office Action at page 8). The Office's contention, however, does not find support in the teachings of the prior art.

First, as stated above, Alexander merely teaches that the long-chain triglycerides can be provided as particular plant oils, and fails to teach or suggest a conversion product which might result in a mixture of fatty acids containing the particular amounts of DHA and EPA claimed in the present application.

Second, even *arguendo* that the metabolized products of the composition disclosed by the prior art should be brought into the picture when considering the novelty and unobviousness of the invention, it has to be emphasized that such a mixture of metabolized products resulting from the conversion of Alexander's composition is totally different from the composition of the present application.

In fact, contrary to the Examiner's allegation, Alexander's composition has a fat content of about 42% (*see* the Table on page 7) or 30 to 44% fat content (*see* claim 4). Further, the composition of Alexander has a long-chain triglyceride content of 40 g/L and a total fat content of 50 g/L (*see* Table on page 7). Thus, the average value for long-chain triglyceride content, (which seems to be the source for α-linolenic acid) is about 34%. In other words, starting from an α-linolenic acid content of 4 to 10%, the composition of Alexander contains about 1.3 to 3.4% α-linolenic acid. It should be emphasized that according to Brenna the conversion rate for α-linolenic acid to EPA and DHA is not necessarily 5%, but "below 5% in humans". Nevertheless, solely for the sake of argument, when assuming that the conversion rate is 5%, the resulting content of EPA and/or DHA in the human body would be merely 0.065 to 0.17%, which is certainly outside of the scope of claim 1.

For at least the reasons stated above, the rejection of claims 1, 3, 6, 9, 14-19 and 21 under 35 U.S.C. § 103(a) is improper. Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

B. The Rejection Over Alexander in Light of Brenna in View of Madigan, Heine and The Merck Index

The Office Action, at pages 11-15, rejects claims 1, 3-6, 9-10 and 14-21 under 35 U.S.C. § 103, as allegedly being unpatentable over Alexander *et al.* (EP 0691079 A2; 1996) ("Alexander") in light of Brenna JT ("Efficiency of Conversion of [alpha]-Linolenic Acid to Long Chain n-3 Fatty Acids in Man", *Current Opinion in Clinical Nutrition and Metabolic Care, 5(2)*:127-132, March 2002; abstract only) ("Brenna"), in view of Madigan *et al.* ("Dietary Unsaturated Fatty Acids in Type 2 Diabetes", *Diabetes Care 23*:1472-1477; 2000) ("Madigan"),

Heine *et al.* ("Linoleic-Acid-Enriched Diet: Long-Term Effects on Serum Lipoprotein and Apolipoprotein Concentrations and Insulin Sensitivity in Noninsulin-Dependent Diabetic Patients", *Am J Clin Nutr, 49(3)*:448-456; 1989, Abstract Only) ("Heine") and the Merck Index ("Citric Acid", Monograph 2328, 1989; page 363). Applicant respectfully traverses this ground of rejection.

The additional references, Madigan, Heine and the Merck Index, do not remedy the deficiencies of Alexander and Brenna demonstrated above, as none of these references discloses a composition comprising 0.5 to 2% eicosapentaen acid and/or docosahexaen acid, as claimed in the present application. Accordingly, the rejection is improper.

Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

C. The Rejection Over Alexander in Light of Brenna and Further in View of Bell and Mendy

The Office Action, at pages 15-17, rejects claims 1, 3-6, 9, 11-19 and 21 under 35 U.S.C. § 103, as allegedly being unpatentable over Alexander *et al.* (EP 0691079 A2; 1996) ("Alexander") in light of Brenna JT ("Efficiency of Conversion of [alpha]-Linolenic Acid to Long Chain n-3 Fatty Acids in Man", *Current Opinion in Clinical Nutrition and Metabolic Care, 5(2)*:127-132, March 2002; abstract only) ("Brenna"), and further in view of Bell *et al.* (WO 97/38593) ("Bell"), and Mendy (US Patent No. 4,407,821) ("Mendy"). Applicant respectfully traverses this ground of rejection.

The additional references, Bell and Mendy, do not remedy the deficiencies of Alexander and Brenna demonstrated above, as none of these references discloses a composition comprising 0.5 to 2% eicosapentaen acid and/or docosahexaen acid, as claimed in the present application. Accordingly, the rejection is improper.

Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

CONCLUSION

All of the stated grounds of rejection have been properly traversed or rendered moot. Thus, the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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